Remarks/Arguments:

Applicants wish to thank Primary Examiner Olga N. Chernyshev, Ph.D., for the instant notice, providing for timely reply to address the issues raised, therein.

Claims 1-15 and 17-31 are pending, with claims 11, 12, and 21-26 being withdrawn pursuant to restriction—the withdrawn claims being so identified, herewith, as required in the PTO notice.

Claim 16 is cancelled, without prejudice or disclaimer.

The claims are presently amended by narrowing "neurodegenerative disease" to "Alzheimer's disease," by deleting the recited "fragment, or derivative, or variant," and to reflect the sequence identifier "SEQ ID NO:" required by the PTO Rules. Additionally, preferred subject matter is excised from the claims of record and made the subject of newly presented claims, i.e., (new) claims 27-30.

Amended drawing figures are submitted with the aforesaid Amendment—concurrently filed in the PTO—in compliance with the instant notice.

An amended Sequence Listing (on paper and in CRF), accompanied by the requisite statement under PTO Rule 821(g) and amendment entering the Sequence Listing, are concurrently filed in the PTO, in compliance with the instant notice.

The specification is amended, hereby, to be commensurate with the aforesaid amendments to the drawings and the Sequence Listing.

Claims 8-10 were rejected under 35 USC 101 for allegedly defining non-statutory subject matter. Reconsideration is requested.

The instant amendment adds the wording "isolated" to the rejected claims. Thereby, the presently claimed subject matter distinguishes naturally occurring material. Withdrawal of the rejection appears to be in order.

Claims 1-10 and 13-20 were rejected under 35 USC 101 and 35 USC 112, ¶1, for allegedly lacking utility/enablement-of-use. Reconsideration is requested.

First of all, the rejections are rendered moot to the extent supported allegations of lack of utility/enablement-of-use with respect to "neurodegenerative disease" and "fragment, or derivative, or variant." None of the present claims recites "neurodegenerative disease" or "fragment, or derivative, or variant."

Secondly, with respect to protein/gene "TARPP" and "Alzheimer's disease" the statutory requirements for utility/enablement-of-use are satisfied. Protein TARPP is differentially expressed in patients suffering from Alzheimer's disease (AD) compared to healthy controls, as described in the subject application (page 5, first full paragraph, Figure 2, and Figure 3). The differential expression of TARPP is proven by quantitative RT-PCR (see page 28, bottom, of the subject application).

For example, in accordance with the presently disclosed and claimed invention TARPP has utility as a diagnostic marker for Alzheimer's disease, which is performed by determination and comparison of the level of TARPP in Alzheimer's disease patients and healthy controls, as described in the subject application (Figures 2 and 3, Tables 1 and 2). Tables 1 and 2 unequivocally demonstrate that the level of TARPP protein in a Alzheimer's disease patients is higher than the level in control individuals (Table 1: control patients' level is 0.47-1.39 and AD patients' level is 1.34-4.11; Table 2: control patients' level

is 1.1-1.76, AD patients' level is 1.21-5.51). This means TARPP can be utilized as a marker, i.e., a diagnostic tool. Furthermore, the use of TARPP as a screening target is disclosed in the subject application (page 22, bottom, to page 24).

This identified, disclosed, and confirmed relationship between the TARPP gene/protein, on the one hand, and Alzheimer's disease, on the other, clearly demonstrates §101 utility and, so, consequentially §112, ¶1, enablement of use. Withdrawal of the rejections appears to be in order.

Additionally, applicants note that the rejection characterizes the protein recited in the rejected claims as an "orphan protein." With all due respect, this characterization is incorrect.

Claims 9 and 10 were rejected under USC 112, ¶1, for allegedly lacking written descriptive support. Reconsideration is requested.

The rejection is based on alleged lack of descriptive support for "fragments, derivatives or variants of SEQ ID NO: 1" (Office Action mailed August 15, 2006, page 9). Since "fragments, derivatives or variants of SEQ ID NO: 1" are not found in presently amended claims 9 and 10, as indicated above, rendering the rejection moot. Accordingly, withdrawal of the §112, ¶1, rejection for alleged lack of descriptive support appears to be in order.

Claims 4 and 13-19 were rejected under USC 112, ¶2, for allegedly being indefinite. Reconsideration is requested.

According to rejection, reciting the phrase "under stringent condition" renders claim 4 indefinite. Since the phrase is not recited in presently amended claim 4, the rejection of the claim is rendered moot.

According to rejection, the rejected claims are allegedly indefinite for omitting essential steps. First of all, each of the claims as rejected and as amended does, in fact, "contain . . . the step that allows achieving the goal stated in the claim preamble" (Office Action, page 12). In any event these allegedly essential steps omitted from the rejected claims need not be recited in order to satisfy the requirements of §112, ¶2.

A patent applicant has the prerogative of claiming "less than the entire invention." *Andrew Corp. v. Gabriel Electronics, Inc.*, 6 USPQ2d 2010, 2014 (Fed. Cir. 1988). A "patentee may claim the whole or only part of his invention." *McLain v. Ortmayer*, 141 U.S. 419, 423-24 (1891). It "is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter." *Bendix Corp. v. United States*, 204 USPQ 617, 621 (Ct. Cl. 1979). *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991) (following *Bendix Corp.*). Explaining *how* the invention is to be practiced is the function of the specification; the function of the claims is to define the legal limits of the invention. *In re Roberts*, 176 USPQ 313, 315 (CCPA 1973).

A §112, ¶2, rejection of method claims is not supported merely by alleging there are "omitted steps" that one skilled in the art would need to practice the invention. It "is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter." *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991). Explaining how the invention is to be practiced is the function of the specification; the function of the claims is to define the legal limits of the invention. *In re Roberts*, 176 USPQ 313, 315 (CCPA 1973).

More importantly, however, applicants have the prerogative of claiming "less than the entire invention." *Andrew Corp. v. Gabriel Electronics, Inc.*, 6 USPQ2d 2010, 2014 (Fed. Cir. 1988). Indeed, it has been a long-held principle of United States patent law, established over 100 years ago by the Supreme Court of the United States, that an applicant for patent "may claim the whole *or only part* of his invention. *McLain v. Ortmayer*, 141 U.S. 419, 423-24 (1891)(*emphasis, added*).

Fore the foregoing reasons, the rejection under §112, ¶2, is overcome. Accordingly, withdrawal of the rejection appears to be in order.

Claims 9 and 10 were objected to under 37 CFR 1.75 for allegedly being duplicates of one another. Reconsideration is requested.

Presently amended claims 9 and 10 define a "diagnostic target" and a "screening target," respectively. A diagnostic target is used in a method to detect —typically ex vivo—the presence or absence of a substance, detection of which indicates the subject is suffering from a disease; whereas, a screening target is used in a method that screens a mixture for agents—substances that interact with the screening target—useful as, e.g., a diagnostic target, drug, etc. Applicants submit that the diagnostic target and screening target of present claims 9 and 10, respectively, are used distinctly different methods, as would be readily apparent to one of ordinary skill in the art.

Request for Examiner's Initialed Form PTO 1449

An Information Disclosure Statement (IDS), including completed form PTO 1449, corresponding international search report (ISR), and copies of the cited references, was filed in the PTO. The submitted PTO form 1449, initialed by the Examiner, was attached to the Office Action mailed August 15, 2006;

however, a line was drawn through the cited reference AE, indicating that the reference was not considered by the examiner, as confirmed in the body of the Office Action, itself.

With all due respect, the stated reasons for not considering the reference exalt form over substance. In any event, under established PTO procedure the examiner cannot refuse to consider reference AE.

In accordance with Manual of Patent Examining Procedure (MPEP) 609.03 (Information Disclosure Statements in National Stage Applications) (emphasis added):

> The examiner will consider the documents cited in the international search report in a PCT national stage application when the Form PCT/DO/EO/903 indicates that both the international search report and the copies of the documents are present in the national stage file. In such a case, the examiner should consider the documents from the international search report and indicate by a statement in the first Office Action that the information has been considered.

Reference AE was "cited in the international search report in a PCT national stage application when . . . both the international search report and the cop[y] of the document[] are present in the national stage file," in compliance with MPEP 609.03. As such, the examiner has no discretion in the matter: compliance being satisfied, MPEP 609.03 requires that the examiner "will consider [reference AE] "and indicate [on the record] that the information has been considered." Moreover, reference AE was listed, separately, on the Form PTO 1449, accompanying the IDS.

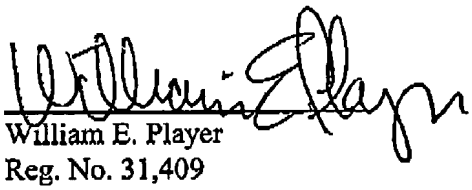
Accordingly, the examiner is requested to mark and initial the submitted Form PTO 1449 to show that the reference at issue was considered and return the initialed Form so marked to applicants' undersigned representatives.

Attorney Docket No. P67772US1
Application No. 10/509,950

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By 
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